MAMMOGRAPHY UPDATE

(Contact Shanna Farish for more information)

RECENTLY ASKED QUESTIONS CONCERNING THE OCTOBER 28, 2002 REQUIREMENTS FOR MAMMOGRAPHY:

For some reason, many sales-people have been informing mammographers that their machines will not pass the 2002 requirements, and they will either have to replace them or quit performing mammography. AND, it is not only sales-people saying these things; repair-people called in to fix something show the mammographers problems with their machine in passing the new requirements. Most of the regulations are written in a way, no one person would agree to what they mean. So the FDA has created guidelines for the inspectors to follow. So please don't get excited and replace your machine or quit doing mammography. Call me first.
The following requirement has been the most commonly used reason when equipment replacement is suggested:

October 28, 2002 Application of Compression:

A. Requires an initial power driven compression, activated by hands free controls operable from both sides of the patient; and
B. Requires fine adjustment compression controls operable from both sides of patient.

GUIDANCE:
A single foot control passes if it is operable from both sides of the patient. Fine compression can be achieved by tapping a foot pedal as with the GE 500T and 600T that do not have a fine compression device. If a tech is having problems using the foot pedal for the fine compression, these machines have controls that can be tweaked by the service rep to make it easier.

Notable findings during the past year of inspections:

1. Fisher Athena Mammography Units: I have found two of the older units that failed to pass the resolution test requirements of the state. They passed last year, but with blossoming focal spots the resolution slowly gets worse. The FDA requires 13 line pairs per millimeter parallel to the plane of the tube and 11 line pairs per millimeter perpendicular to the plane of the tube. The state requires at least 12 line pairs per millimeter either way. Please review your physicist report. It was found

that at least one physicist had been passing these findings. When their results are 11 parallel, it should be investigated because the average line pairs parallel on a mammography unit is between 16 and 20. It is always lower perpendicular.

2. The new mammography inspector found two facilities, which received Level I (the highest) violations from the FDA, because they had not done their phantom images for a month. Remind techs to not become careless about their QC.

3. If you get a new radiologist, make sure all the documentation is in place. If he/she is just out of residency, make sure they have a letter from their residency school documenting their training, experience, and education in mammography. If they are from another facility, where they have passed a FDA inspection, make sure your books have all of their documentation in place. For some reason, they think if they passed over there, it makes them fine over here. One piece of documentation that is usually missing is their continuing experience of interpreting at least 960 mammograms in the past two years.

4. If you change report transcription employees or companies, make sure they are aware of the "birad requirements." Radiologists usually just say the birad number rather than the required verbiage. The transcriptionist types in the verbiage associated with that number. The verbiage must be present, not everyone, including referring physicians know what these numbers stand for. BIRADS: Negative, Benign, Probably Benign, Suspicious, Highly Suggestive of Malignancy.

SOME NEW AND HELPFUL THINGS:

Facilities should be logging occurrences that require the use of the infection control procedure required by MQSA. This log is not for every cleaning, but when body fluids come into contact with the mammography unit and is cleaned with a disinfectant that is documented in the Infection Control SOP.

Make sure all consumer complaints are being filed and retained for at least 3 years.

Mammography medical records must be retained for at least ten years unless there is a more recent mammogram, then the previous records can be discarded after not less than 5 years.

Facilities must grant a request for permanent or temporary transfer of mammography medical records by the patient or by someone acting upon her behalf.

Original films must be transferred. Facility can make copies to keep in their files, but only original films are to be transferred for comparison study.

Appropriate fees may be charged for the transfer but must be limited to the actual cost for transfer. Charges for transfer of records may include items such as administrative time costs incurred in logging the request, retrieving the films and reports, packaging and mailing; cost of packaging material and cost of transfer (mail charges). If requested by the patient, the facility must produce documentation (itemized bill) that shows the charges do not exceed the costs associated with the service.